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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,141	07/25/2003	Juan Carlos de la Torre	TSRI 465.0 D2	4125

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THE SCRIPPS RESEARCH INSTITUTE
OFFICE OF PATENT COUNSEL, TPC-8
10550 NORTH TORREY PINES ROAD
LA JOLLA, CA 92037

EXAMINER	
CHEN, STACY BROWN	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,141	DE LA TORRE, JUAN CARLOS	
	Examiner	Art Unit	
	Stacy B Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *5-59* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's preliminary amendment filed July 25, 2003 is acknowledged and entered. Claims 5-59 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-8, 22-24 and 34, drawn to a polynucleotide, vector and host cell encoding human Borna disease virus (BDV) p16, classified in class 536, subclass 23.72.

II. Claims 9-11, 25-27 and 34, drawn to a polynucleotide, vector and host cell encoding human BDV p56, classified in class 536, subclass 23.72.

III. Claims 12-15, 28-30 and 34, drawn to a polynucleotide, vector and host cell encoding human BDV p40, classified in class 536, subclass 23.72.

IV. Claims 16-18, 31-33 and 34, drawn to a polynucleotide, vector and host cell encoding human BDV catalytic domain of the L polymerase protein, classified in class 536, subclass 23.72.

V. Claims 19-21, drawn to a vector encoding human BDV p24, classified in class 536, subclass 23.72.

VI. Claims 35-38, drawn to a human BDV p24 polypeptide, classified in class 424, subclass 204.1.

VII. Claims 39-42, drawn to a human BDV p16 polypeptide, classified in class 424, subclass 204.1.

VIII. Claims 43-46, drawn to a human BDV p56 polypeptide, classified in class 424, subclass 204.1.

IX. Claims 47-50, drawn to a human BDV p40 polypeptide, classified in class 424, subclass 204.1.

X. Claims 51-54, drawn to a human BDV catalytic domain polypeptide of the L polymerase protein, classified in class 424, subclass 204.1.

XI. Claim 55, drawn to an anti-human BDV p24 polypeptide antibody, classified in class 424, subclass 159.1.

XII. Claim 56, drawn to an anti-human BDV p16 polypeptide antibody, classified in class 424, subclass 159.1.

XIII. Claim 57, drawn to an anti-human BDV p56 polypeptide antibody, classified in class 424, subclass 159.1.

XIV. Claim 58, drawn to an anti-human BDV p40 polypeptide antibody, classified in class 424, subclass 159.1.

XV. Claim 59, drawn to an anti-human BDV catalytic domain polypeptide of the L polymerase protein antibody, classified in class 424, subclass 159.1.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-V (polynucleotides), Groups VI-X (polypeptides), and Groups XI-XV (antibodies) are patentably distinct products.

a) The polynucleotides of Groups I-V, and the polypeptides of Groups VI-X are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are

structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. While the polypeptide of Groups VI-X can made by methods using some, but not all, of the polynucleotides that fall within the scope of Groups I-V, it can also be recovered from a natural source using biochemical means. For instance, the polypeptides can be isolated using affinity chromatography. For these reasons, the inventions of Groups I-V and Groups VI-X are patentably distinct. Furthermore, searching the inventions of Groups I-V and Groups VI-X together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I-V and Groups VI-X have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I-V and Groups VI-X together.

b) The polypeptides of Groups VI-X and the antibodies of Groups XI-XV are patentably distinct for the following reasons. While the inventions of both Groups VI-X and Groups XI-XV are polypeptides, in this instance the polypeptides of Groups VI-X are single chain molecules that function as an enzyme, whereas the polypeptides of Groups XI-XV encompass antibodies

including IgG which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptides of Groups VI-X and the antibodies of Groups XI-XV are structurally distinct molecules; any relationship between the polypeptides Groups VI-X and antibodies of Groups XI-XV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide. Therefore the polypeptides and antibodies are patentably distinct. Furthermore, searching the inventions of Groups VI-X and Groups XI-XV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Groups XI-XV. Furthermore, antibodies which bind to an epitope of a polypeptide of Groups VI-X may be known even if a polypeptide of Groups VI-X is novel. In addition, the technical literature search for the polypeptides of Groups VI-X and the antibodies of Groups XI-XV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

c) The polynucleotides of Groups I-V and the antibodies of Groups XI-XV are patentably distinct for the following reasons. The antibodies of Groups XI-XV include, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6

complementarity determining regions (CDRs). Polypeptides, such as the antibodies of Groups XI-XV which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Groups I-V will not encode an antibody of Groups XI-XV, and the antibodies of Groups XI-XV cannot be encoded by a polynucleotide of Groups I-V. Therefore the antibody and polynucleotide are patentably distinct. The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups I-V and Groups XI-XV would impose a serious search burden since a search of the polynucleotides of Groups I-V would not be used to determine the patentability of an antibody of Groups XI-XV, and vice-versa.

Inventions I, II, III, IV and V are drawn to distinct polynucleotides. Inventions VI, VII, VIII, IX and X are drawn to distinct polypeptides. Inventions XI, XII, XIII, XIV and XV are drawn to distinct antibodies.

d) The various polynucleotides are related in that they are from the same virus, however, they encode distinct polypeptides/open reading frames: p16, p24, p56, p40 and the catalytic domain of the L polymerase protein. These open reading frames have different amino acid sequences, thus encoding different proteins. Each of the proteins will elicit different antibodies due to their varying amino acid sequences. Searching each open reading frame would impose a serious search burden since a search for one open reading will not reveal the other open reading frames due to their different sequences.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Conclusion

3. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

SBC
Stacy B. Chen
September 8, 2004

James C. Housel 9/20/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600